Delaware Joins Other States in Settlement With Pharmaceutical Company Regarding the Marketing of Over-The-Counter Drugs

Forty-three states, including Delaware, have reached a settlement with Johnson & Johnson Consumer Inc. and Johnson & Johnson over allegations that the manufacturers inaccurately promoted their over-the-counter (OTC) drugs as complying with federally mandated current Good Manufacturing Practices despite some manufacturing facilities did not comply.

The state alleged that between 2009 and 2011, McNeil Consumer Healthcare Division, now a division of Johnson & Johnson Consumer Inc., violated state consumer protection laws by misrepresenting the current Good Manufacturing Practices (cGMP) compliance and the quality of their OTC drugs, and represented that these OTC drugs had sponsorship, approval, characteristics, ingredients, uses, benefits, quantities, or qualities that they did not have.

McNeil's alleged quality control lapses resulted in recalls of drugs manufactured between 2009 to 2011including Tylenol, Motrin, Benadryl, St. Joseph Aspirin, Sudafed, Pepcid, Mylanta, Rolaids, Zyrtec, and Zyrtec Eye Drops, several of which are indicated for pediatric use.

The consent judgment entered into by the states and McNeil require that marketing and promotional practices do not unlawfully promote OTC drug products. Specifically, McNeil:

- Shall not represent on its websites that McNeil's OTC Drug Product facilities meet cGMP as outlined by the FDA

if McNeil has had a Class I or Class II Recall of OTC drug products within the prior 12 months. Class I recalls involve situations in which there is a reasonable probability that the use of or exposure to a violative product will cause serious adverse health consequences or death. Class II recalls involve situations in which use of or exposure to a violative product may cause temporary or medically reversible adverse health consequences, or where the probability of serious adverse health consequences is remote;

- Shall not fail to follow its internal standard operating polices regarding whether to open a Corrective Action/Preventive Action plan (CAPA) during the manufacture of an OTC drug; and
- Shall not fail to provide information to participating Attorneys General within sixty (60) days of a written request regarding the identity of wholesalers or warehouses to which any OTC drugs that were subject to a recall were distributed in their State.

The settlement also requires Johnson & Johnson to pay $629,569.51 to the Delaware Consumer Protection Fund, which funds work on consumer fraud and deceptive trade practice matters and other consumer-oriented investigations and legal actions. Johnson & Johnson will pay a total of $33 million to states as part of the settlement.

Delaware sat on the executive committee of the multi-state group that investigated the allegations and reached the settlement.

Deputy Attorney General Christian Wright led Delaware’s efforts in the investigation.